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A single-surgeon randomized trial comparing three meshes in lichtenstein hernia repair: 2- and 5-year outcome of recurrences and chronic pain

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ABSTRACT

Background: Chronic pain may be a major long-term problem related to mesh material and operative trauma in inguinal hernioplasty.
Study design: Lichtenstein hernioplasty was performed under local anaesthesia in 312 patients by the same surgeon and technique between 2003 and 2005. The patients were randomized to receive a partly absorbable polypropylene-polyglactin mesh (Vypro II® 50 g/m^2, 104 hernias), a lightweight polypropylene mesh (Premilene Mesh LP® 55 g/m^2, 107 hernias) or a conventional densely woven polypropylene mesh (Premilene® 82 g/m^2, 101 hernias). The 2- and 5-year recurrences and pain scores were analysed.
Results: Patient's characteristics and the mean duration of operation (30–32 min) were similar between the three groups. After two years, there were 6 recurrences (2 in each group) of which 3 patients were re-operated. A feeling of a foreign body and sensation of pain were comparable with all meshes. After five years, overall recurrence rate was 10/312 (3.2%) with only 4 re-operations. A feeling of a foreign body (6.5–8.1%), chronic pain (13–23%) as well as use of analgesics (0–2.9%) were similar in all groups.
Conclusion: There were no statistical differences between the three meshes in pain, a feeling of a foreign body or use of analgesics after 5 years of Lichtenstein hernioplasty, when the same surgeon operated all patients with exactly the same surgical technique.
Clinical Trial Register: NCT01295437.

1. Introduction

Chronic pain after Lichtenstein hernioplasty may occur in 10–30 percent of patients.[1–4] Pain is often reported to be neuropathic in character, related with younger age, to exist during physical activity and it is more often associated with recurrent hernia surgery.[1–4]The etiological factors of pain include irritation of inguinal nerves by sutures or mesh, inflammatory reaction against the mesh or simply scar tissue.[5–9] Identification and preservation of inguinal nerves during surgery may prevent or decrease the frequency of chronic pain. [10,11] Pain reaction is, however, related to both the patient and surgical factors. Patients with a high preoperative physical activity score and high pain response to a standardized heat stimulus may have low frequency of post-hernioplasty pain.[12] Age below median, absence of a visible bulge before the operation, recurrent hernia repair or history of moderate to severe pre-operative groin pain are some factors that are associated with increased chronic post-operative pain.[13]

In randomized multi-centre studies, use of lightweight meshes may be associated with significantly less pain during exercise and less feeling of a foreign object compared to standard heavy meshes at short-term (<6 months) follow-up.[14–16] The recurrence rate after use of low-weight mesh may be a little bit higher than after high weight mesh hernioplasty.[14] There are very few reports of well controlled studies on low-weight meshes with long-term follow-up. In a study of 590 patients with 3 years follow-up, Bringman and co-workers showed no differences in neuralgic pain, hypoaesthesia or hyperaesthesia between the high-weight and low-weight mesh groups.[17] There were no major differences in response to the pain questionnaire, except that fewer men with low-weight mesh had pain when rising from lying down to a sitting-up position.

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Significantly more men in the standard mesh group could feel the mesh in the groin: 22.6% versus 14.7%.[17] More importantly, this study with longer follow-up showed no difference in recurrence rates with either high-weight or low-weight meshes[17] .European hernia guidelines for open hernia repair emphasize a Grade A recommendation for the use of synthetic non-absorbable flat mesh or composite mesh with a non-absorbable component. Almost all the previous controlled trials have included multiple surgical centres, various anaesthetic techniques and many operating surgeons. There is only one randomized single-centre trial (one surgeon, Lichtenstein under general anaesthesia), which showed that there was no difference in post-operative pain or recurrence between titanium-coated lightweight mesh compared with standard polypropylene mesh at the 1-year follow-up.[18] The aim of the present single-centre study was to compare the long-term results of Lichtenstein hernioplasty using three different meshes, while all other operative parameters including surgeon's experience were exactly the same. The immediate post-operative outcome and 2-year results of this study have been published earlier.[19] Now we report the 2- and 5-year outcome of recurrences and frequency of chronic pain after enrolling more patients into this randomized trial.

2. Methods

The study was conducted between March 2003 and December 2005 in the ambulatory surgical units of two hospitals. The study subjects ($n = 312$) were >18 years old with elective inguinal hernias. The inclusion criteria were uni- or bilateral primary or recurrent inguinal hernia. The previous repairs did not include mesh hernioplasty. Patients fulfilling the day-case surgery criteria received written and oral information about the aims and content of the study in accordance with the Helsinki Declaration. The ethics committee in our hospital approved the study protocol and the study was registered in Clinical Trials Register (NCT01295437). The exclusion criteria were femoral hernia, emergency operation, strangulated hernia and allergy to polypropylene. The preliminary data of the first 228 patients was published previously.[19]

Randomization was performed using numbered and sealed envelopes that were opened during the operation (Fig. 1). The patients and staff conducting the post-operative assessment were both unaware of the treatment allocation. The patients were randomized to receive a conventional densely woven polypropylene mesh (Premilene® 82 g/m^2, B. Braun, Germany), a lightweight polypropylene mesh (Premilene Mesh LP® 55 g/m^2, B. Braun, Germany) or a partly absorbable polypropylene-polyglactin mesh (Vypro II® 50 g/m^2, Ethicon, Hamburg, Germany). In patients with bilateral hernias (4 patients), a different type of mesh was placed on each side; randomization determined which side each mesh was implanted.

The patients were operated by the same senior consultant surgeon (HP) with good experience of inguinal hernias. The tension-free hernioplasty was performed by using a 9 × 13 cm trimmed mesh with a keyhole. The sac of indirect hernia was either resected or just inverted into the abdomen. If the hernia sac was large and direct, it was inverted with absorbable 2-0 Dexon® (United States Surgical, Norwalk, CT 06856, USA). The mesh was trimmed and placed between the conjoint tendon, the inguinal ligament, the pubic bone and the internal oblique aponeurosis.[19,20] Mesh was fixed by using 3-0 Dexon® sutures. The ilioinguinal, genitofemoral and iliohypogastric nerves were identified if possible and carefully preserved. Care was taken not to involve the nerves within the sutures. The procedure was always performed under local anaesthesia as an outpatient surgery. Local infiltration anaesthesia was a 1:1 mixture of bubivacaine (Marcain 5 mg/ml, AstraZeneca, UK) and Citanest-adrenalin (10 mg/ml + 5 μg/ml, AstraZeneca, UK) with an average total volume of 40–60 ml.[19] After surgery the patient was followed up for 60–120 min to observe possible wound haemorrhage and then discharged. No prophylactic antibiotics were used. A 0.5–1.0 mg bolus of intravenous alfentanil was administered (Rapifen, AstraZeneca, UK), if the patient felt pain during the operation. Ibuprofen or paracetamol plus codeine were prescribed for post-operative pain.

Pre-operative pain scores on a visual analogue scale (VAS) were measured for all patients during rest and moving (normal walking), as well as all patients completed a standard questionnaire form of previous disease history. Operative details were recorded including the type and size of the hernia, volume of local anaesthetic, the operation time, bleeding and pre-operative medication. All post-operative complications were recorded as published previously.[19] The patients were telephoned with a set of questions at 1, 7, and 30 days, and 6, 12, 24 and 56 months after surgery. Telephone questionnaire was performed by a dedicated research nurse blinded to the type of mesh. Pain scores (VAS) were also recorded post-operatively at the same time points. Patients who reported suspicion of recurrence or chronic pain (VAS > 3) were recalled and examined clinically by the non-operating surgeon (AL). Chronic pain, need of medication, feeling of foreign object and satisfaction of the procedure was recorded at each time interval. The questions were based on the study of the Danish Hernia Database.[2] The study flow and patients' dropping out of the trial are seen in Fig. 1.

According to the power calculations, 65 subjects per treatment group were needed for the study to achieve a statistical power of 0.90 with an α of 0.05 (two tailed). The calculations were made for the duration of pain at one year after surgery, considering a 20% difference between the groups as clinically significant (incidence of chronic pain at 12 months: heavyweight mesh 25%, lightweight mesh or Vypro II mesh 5%). Allowing a drop-out rate of 20–30% during 5-year follow-up, the study was set up to include randomization of >300 patients. The data analysis was carried

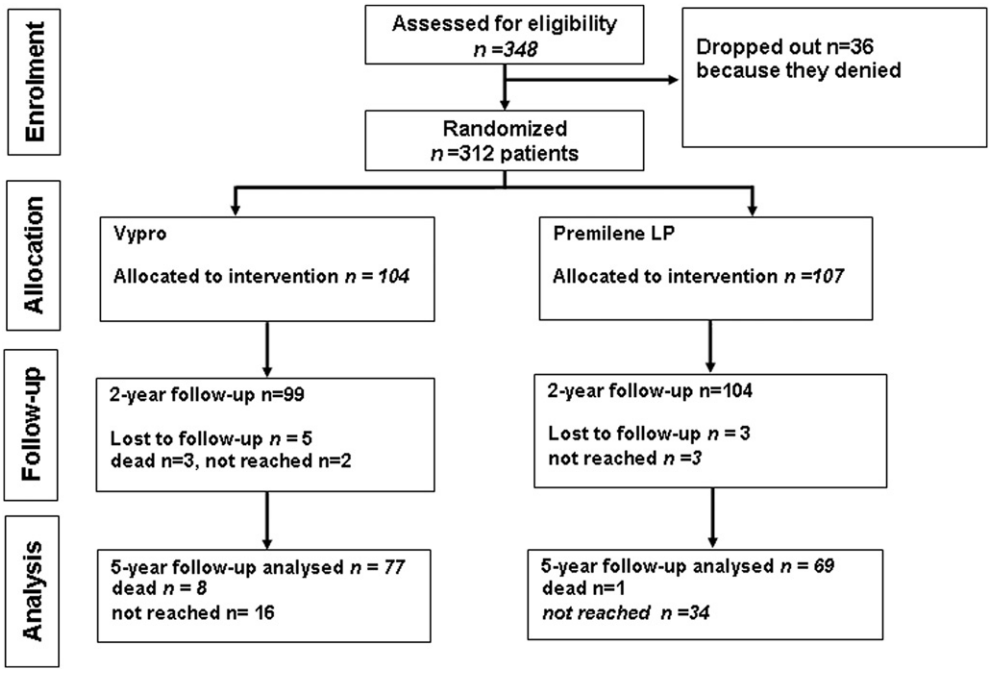

Fig. 1. Flow chart of the study.

out using SPSS for Windows, Release 10.0 (SPSS, Chicago, Illinois, USA). The statistical evaluation was performed with ANOVA and khii-2 test with Yates correction between the groups.

3. Results

Because 82 patients (26%) were lost during the 5-year follow-up, the final analysis included a total of 220 hernias (Fig. 1). There were no significant differences in patient's characteristics between the three treatment groups (Table 1). Ten patients remained at hospital overnight (6 postoperative haematomas, 4 social reasons). The mean operating time was statistically similar between the study groups (Table 1). After two years of follow-up, two patients in each study groups had recurrent hernia with one re-operation in each group (Table 2). Feeling of pain at exercise varied non-significantly from 4.0 to 7.0% in the three study groups. Only two patients needed regular analgesics after two years of surgery. A feeling of foreign body of the patients varied also non-significantly from 17 to 26% (Table 2).

There were no differences in the 5-year convalescence between the treatment groups (Table 2). Recurrent hernias were found in 10 patients (2.2%) with no difference between the study groups. During 5 years, the four re-operations confirmed two lateral (one Vypro, one Premilene LP) and two medial (one Premilene LP, one Premilene) recurrences. Low-weight meshes did not have any increased risk for recurrences for obese patients, because the body mass index of patients with recurrent hernias varied between 25 and 28 kg/m^2. After five years of follow-up, a feeling of pain at exercise and use of analgesics for groin pain was rare and not dependent on certain mesh use (Table 2). A feeling of a foreign object was more common after two years (17–24%) than five years (6–8%).

Fig. 2 shows that the early and late post-operative pain scores were similar between the study groups. There was a tendency (non-significant) towards increased pain following the use of a conventional mesh after the first and second study year. After five years of follow-up, no significant differences in the pain scores were found (Fig. 2).

4. Discussion

The two most important long-term outcome measures after Lichtenstein hernioplasty are the recurrences and chronic pain. There are very few 5-year results of well-controlled randomized clinical trials using lightweight meshes versus standard heavyweight polypropylene meshes. The present study showed that there were no significant differences in pain scores, recurrences, patient's discomfort or need of analgesics between standard, lightweight or partially absorbable meshes when same surgeon operated the patients with the same surgical technique and anaesthesia method. Similar results have been published earlier in Lichtenstein hernioplasty[18] and laparoscopic hernia repair[21] after one-year follow-up. Also a feeling of foreign body reaction in the groin area was similar between the meshes and decreased by more than a half when enough time was elapsed. According to the recent panel discussion, a good mesh will have negligible foreign body reaction with no pathologic fibrosis.[22] Very fresh meta-analysis of the use of lightweight versus heavyweight mesh in open inguinal hernia repair indicated that the use of lightweight mesh was not associated with an increased risk of hernia recurrence, but lightweight mesh reduced the incidence of chronic pain.[23]

The surgeon should have the ability to choose a mesh device suited to each patient's particular hernia condition. An ideal mesh for repair of inguinal hernia would have the benefits of both heavyweight and lightweight meshes, such as the strength of a heavyweight mesh and the flexibility of a lightweight mesh with none of the adverse effects.[22] Our 5-year results indicated that most

Table 1
Patient's characteristics and operative data described as means ± SD or raw numbers.

	Vypro $n = 104$	Premilene LP $n = 107$	Premilene $n = 101$	p-Value
Male/Female	98/6	101/6	93/8	0.7519
Mean age (±SD)	58 ± 14	59 ± 13	61 ± 15	0.9999
BMI (±SD)	23 ± 4.0	24 ± 3.1	24 ± 3.5	0.0653
Left/right	49/55	62/45	60/41	0.1517
Direct/indirect	51/49	50/49	37/57	0.1892
Combined	4	8	7	0.4965
Size of defect (cm) < 1.5	20	19	22	0.7613
1.5–3	45	50	52	0.4971
>3	39	38	27	0.2207
Primary/ Recurrent	95/9	95/12	90/11	0.7740
Mean operation time (±min)	31 ± 8	32 ± 10	30 ± 7	0.3481

Table 2
Long-term results after 2 and 5 years (%).

	Vypro ($n = 104$)	Premilene LP ($n = 107$)	Premilene ($n = 101$)	p-Value
2 years:				
Number of patients	99	104	99	
Recurrences	2 (2.0)	2 (1.9)	2 (2.0)	0.9983
Re-operated	1 (1.0)	1 (1.0)	1 (1.0)	0.9992
Pain feeling	6 (6.0)	7 (7.0)	4 (4.0)	0.6898
Analgesic use				
Daily	1 (1.0)	1 (1.0)	0 (0)	0.6115
Sometimes	5 (5.0)	2 (2.0)	2 (2.0)	0.3354
Feeling of foreign body	17 (17)	26 (26)	18 (18)	0.3166
5 years:				
Number of patients	77	69	74	
Recurrences	3 (3.9)	4 (5.8)	3 (0.6)	0.8209
Re-operated	0 (0)	1 (2.9)	0 (0)	0.3531
Pain feeling	10 (13)	16 (23)	12 (16)	0.2544
Analgesic use				
Sometimes	0 (0)	2 (2.9)	2 (2.7)	0.3326
Feeling of foreign body	5 (6.5)	5 (7.2)	6 (8.1)	0.9296

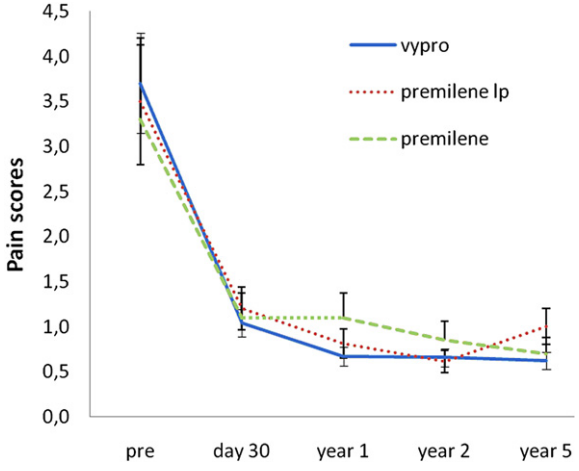

Fig. 2. The mean pain scores of three meshes during 5 years of follow-up.

recurrences were anatomical but not functional in terms of pain and discomfort, since only 4/10 recurrent hernias were re-operated. The recurrences in the present study occurred equally with all meshes. Four additional recurrences were found after 5 years when compared to 2-year results. The body mass index of patients with recurrences were at normal range (<30 kg/m^2), which indicated that obesity was not related to the increased recurrence rate when using lightweight meshes.

The present study also indicated that severe chronic neuralgia was rare and not dependent on mesh material. Some feeling of pain and discomfort was observed between 13 and 23% of patients, but only 4 patients (1.8%) needed occasionally analgesics at 5 years post-operatively. The patients feeling of pain did not decrease between two and five years of follow-up. In fact, after five years even more patients reported some sensation of pain in the groin area although the pain scores between the meshes were similar. When post-operative neuralgia occurred, it usually healed without surgical treatment. No patients were re-operated due to chronic pain in the present series, but triple neurectomy has been suggested in severe cases of chronic pain.[24] In order to eliminate chronic pain and stiffness, permanent mesh fixation should ideally be avoided.[22] Therefore the 3-0 non-continues absorbable sutures were used in the present study. Many recent studies have pointed out that self-adhesive meshes or glue fixation give comparable results as conventional mesh fixation with non-absorbable sutures.[25,26]

One weakness of the present study was, that we did not examine clinically or by ultrasound imaging all 220 patients at 5 years after surgery. Some small, asymptomatic, subclinical recurrent hernias might have been missed. More enrolled patients into this trial would also reveal minor pain score differences between the meshes. The present study was powered to show a 20 percent difference in chronic pain between the three meshes. This is reasonable because many earlier studies have shown that about 30 percent of patients may have some chronic pain after inguinal hernioplasty. If one would goal the study power to 15 percent difference or less, more patients would be needed in each patient group, which means a multi-centre and multi-surgeon study. The only exact way to compare meshes in terms of post-operative pain and discomfort is to keep all other operative parameters unchanged (especially surgeon-related).

To conclude, the present study indicated that mesh material had little effect on postoperative pain and recurrence after five years of Lichtenstein hernioplasty when same surgeon operated all the patients with the same technique. The only variable parameter in the present study was mesh material. Lichtenstein hernioplasty under local anaesthesia was a rapid and effective surgical technique for inguinal hernia repair. Further trials between lightweight and heavyweight meshes are needed to evaluate quality-of-life issues and cost analysis.[23]

Ethical approval

The ethics committee of Etelä-Savo Central Hospital (Mikkeli) has approved this trial. ETMK § 11. Clinical Trials Register NCT01295437.

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Author contribution

Kirsi Rönkä: data collection, manuscript preparation.

Anniina Laurema: data collection, manuscript preparation.

Hannu Paajanen: operation of patients, manuscript preparation.

Conflict of interest

No financial or personal relationship with other people or organisations does exist by any authors of this manuscript.

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